IFW AF #

[2565/94]

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:		
	HAHMANN et al.	Confirmation No.:7106
For:	CLOSURE ELEMENT	Examiner : Sun Kim
		Art Unit : 1723
Filed:	January 18, 2002	
Serial No.:	10/052,768	
Customer No.: 26646		

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Alexandria, VA 22313-1450

APPEAL BRIEF TRANSMITTAL

SIR:

Transmitted herewith for filing in the above-identified patent application, please find an Appeal Brief pursuant to 37 C.F.R. § 1.192(a), in triplicate.

Please charge the Appeal Brief fee of $330.00, and any other fees that may be required in connection with this communication to the deposit account of **Kenyon & Kenyon**, deposit account number **11-0600**.

A duplicate of this Transmittal is enclosed.

Respectfully submitted,

Dated: June 24, 2004

By: _____
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Docket No. 2565/94

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT	:	HAHMANN et al.
SERIAL NO.	:	10/052,768
FILED	:	January 18, 2002
FOR	:	CLOSURE ELEMENT
GROUP ART UNIT	:	1723
EXAMINER	:	Sun Kim

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Date: June 24, 2004

Signature: _____
Thomas C. Hughes (Reg. No. 42,674)

APPEAL BRIEF PURSUANT TO 37 C.F.R. § 1.192(a)

SIR:

In the above-identified patent application ("the present application"), on April 26, 2004, Appellant filed a Notice of Appeal and Request for Extension of Time Pursuant to 37 C.F.R. §1.136 (a) from the final rejection of claims 36 to 38 and 59 to 69 contained in the Final Office Action issued by the United States Patent and Trademark Office ("the PTO") on November 28, 2003. Since the Notice of Appeal was filed on April 26, 2004, the period for filing this Appeal Brief expires on June 26, 2004.

In accordance with 37 C.F.R. § 1.192(a), this brief is submitted in triplicate in support of the appeal of the final rejection of claims 36 to 38 and 59 to 69. For at least the reasons set forth below, it is respectfully submitted that the final rejections of claims 36 to 38 and 59 to 69 should be reversed.

1. REAL PARTY IN INTEREST

The real party in interest in the present appeal is Fresenius Medical Care Deutschland GmbH ("Fresenius") of Bad Homburg in Germany. Fresenius is the assignee of the entire right, title and interest in the present application.

2. RELATED APPEALS AND INTERFERENCES

There are no interferences or other appeals related to the present application "which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal."

3. STATUS OF CLAIMS

Claims 36 to 38 and 59 to 69 are pending in the present.

Claims 1 to 35 and 39 to 58 were previously cancelled.

Claims 36 to 38, 59 to 62 and 65 to 69 were finally rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 4,197,848 ("Garrett et al.").

Claims 36 to 38, 60 to 64 and 66 to 69 were finally rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 4,929,235 ("Merry et al.").

Appellants appeal from the final rejection of claims 36 to 38 and 59 to 69.

A copy of the appealed claims is attached hereto as Appendix A.

4. STATUS OF AMENDMENTS

A Final Office Action was issued in this application on November 26, 2003. The Final Office Action made final the rejections to claims 36 to 38 and 59 to 69.

In response to the Final Office Action dated November 26, 2003, a Reply Under 37 C.F.R. § 1.116 was filed in the USPTO on January 28, 2004. An Advisory Action, as well as a Notice of Non-Compliant Amendment was mailed on February 24, 2004. The Advisory Action refused entry of Appellant's Reply Under 37 C.F.R. §1.116.

On March 12, 2004, a Response to Advisory Action was filed in the USPTO. A second Advisory Action was mailed on March 31, 2004. The second

Advisory Action indicated that the proposed amendments would be entered for the purposes of appeal.

5. SUMMARY OF THE INVENTION

The present invention relates to a closure element having a simple design that can reliably ensure a sterile closure. Page 2, lines 5 to 7. The Specification states that "the closure element includes a wall having a slit-shaped indentation that closes automatically, and when closed forms a germ-proof closure." Page 2, lines 9 to 11. The Specification also states that "[t]here are also fastening means that are adjacent to the wall, so the closure element can be attached to a connection by these fastening means. Page 2, lines 11 to 13. The Specification further states that "[s]uch a closure element according to this invention has a simple design and provides a reliable and sterile seal of a medical object, such as a filter module, during and after sterilization, due to the automatically closing slit-shaped indentation." Page 2, lines 13 to 17. In addition, the Specification states that "[w]hen a suitable connecting element such as a connection of a sterilization device or of a dialysis machine is inserted, the slit-shaped indentation in the closure element according to this invention is opened to fit the shape of the connecting element." Page 2, lines 17 to 21.

The Specification states that "[w]hen the connecting element according to this invention is removed from the closure element, after sterilization or treatment, the slit-shaped indentation closes automatically, thus preventing contamination of the sterilized area as well as leakage from the item sealed with the closure element." Page 2, lines 23 to 27. The Specification also states that "[i]n [one] embodiment, the closure element has an essentially cylindrical shape, and the fastening means are formed by the cylindrical surface and the slit-shaped indentation, arranged on one of the end faces of the cylinder." Page 2, lines 29 to 32. The Specification states that "[s]uch a cap-like design of the closure element has the advantage that the fluid supplied and removed flows along a simple linear path in a passage through the closure element." Page 2, lines 34 to 37. The Specification states that "[t]he development of dead zones can thus be effectively prevented by an appropriate arrangement of the slit-shaped indentation." Page 2, line 37 to page 3, line 2. The Specification states that "[t]his design also prevents

the mixing of different fluids, such as mixtures containing different active ingredients or medicines, that pass through the closure element. Page 3, lines 2 to 5.

The Specification states that "[t]he present invention also concerns the use of a closure element for the sterile closure of connections of medical items." Page 5, lines 4 to 6. The Specification states that "[i]n a preferred embodiment, the medical item is a filter module for dialysis, hemofiltration or ultrafiltration, with the closure element being used for in-line sterilization of the filter module." Page 5, lines 6 to 9. The Specification also states that "[t]he present invention also concerns a medical item with one or more connections for supplying and/or removing a fluid, with at least one connection being provided with a closure element according to this invention." Page 5, lines 16 to 19. In addition, the Specification states that "[t]he medical item may be a filter module for dialysis, hemofiltration or ultrafiltration." Page 5, lines 19 to 20.

6. ISSUES

A. Whether claims 36 to 38, 59 to 62 and 65 to 69 are patentable over Garrett et al.

B. Whether claims 36 to 38, 60 to 64 and 66 to 69 are patentable over Merry et al.

7. GROUPING OF CLAIMS

For purposes of this appeal, all claims do not stand or fall together. Claims 36 to 38, 59 to 62 and 65 to 69 will be argued as one group. Claims 36 to 38, 60 to 64 and 66 to 69 will be argued as a second group.

8. ARGUMENTS

A. The Rejection of Claims 36 to 38, 59 to 62 and 65 to 69 Under 35 U.S.C. § 103(a) as Anticipated by Garrett et al. Should Be Reversed

Claims 36 to 38, 59 to 62 and 65 to 69 stand finally rejected under 35 U.S.C. § 103(a) as unpatentable over Garrett et al. It is respectfully submitted that Garrett et al. does not anticipate claims 36 to 38, 59 to 62 and 65 to 69 for at least the following reasons.

Claim 36 relates to a filter module. Claim 36 recites that the filter module includes a closure element. Claim 36 also recites that a wall is formed in the closure element having an automatically closing slit-shaped indentation forming a germ-proof closure when closed. Claim 36 also recites a means for fastening the closure element to a connecting element disposed adjacent to the wall.

Garrett et al. purport to describe an improved closed irrigation site in a urinary irrigation device. According to Garrett et al., the site is characterized by a rigid lip defining a mouth at the distal end of an irrigation tube, a resilient, impervious membrane against the lip and covering the mouth and having a normally closed, resiliently deformable slit therethrough over the mouth, and a plug or other member securing the membrane against the lip. Garret et al. state that the membrane may be compressed against the lip thereby biasing the slit in a closed position.

The Final Office Action states that "Garrett et al teach a closure element (42, 46) in a medical device comprising a resilient wall (42) with a resiliently deformable slit (56) and a cylindrical integral skirt (46) wherein wall and skirt are made of latex and resilient slit prevents entry of air (see figures 1-4; col. 4, line 37 – col. 5, line 18)." Final Office Action at pages 2 to 3. The Final Office Action also states that "[l]ip (36), inner and outer annulus (34, 38) hold the closure element (42, 46) and thus, satisfies the means for fastening the closure element to a connecting element (see col. 4, lines 23-48)." Final Office Action at page 3. The Final Office Action admits that "[c]laim 36-38, 59-60, 62, 65-66 and 68 essentially differ from the device of Garrett et al in reciting a filter module." Final Office Action at page 3. However, the Final Office Action concludes that "[i]t would have been obvious to a person of ordinary skill in the art to incorporate a closure element of Garrett et al in a common medical filter module such as a dialyzer, hemofilter and ultrafiltration filters with a plurality of connections for providing sterile connections between a tubing and the filter module." Final Office Action at page 3.

Respectfully, Garrett et al. do not render unpatentable claim 36 for at least the reason that Garrett et al. do not disclose, or even suggest, all of the limitations of claim 36. Specifically, Garrett et al. do not disclose, or even suggest, a filter module having a closure element, as recited in claim 36. The Specification states that "Figure 1B shows a housing 20 having an opening 30, for example of a filter module, for accommodating closure element 10 according to this invention." Page 7, lines 18 to 20. The Specification also states that "a closure element

according to this invention has a simple design and provides a reliable and sterile seal of a medical object, such as a filter module, during and after sterilization." Page 2, lines 13 to 16.

In contrast, Garrett et al. purport to describe a closed irrigation site in a urinary irrigation device. Specifically, Garrett et al. states that "FIG. 1 illustrates a urinary drainage system having an adapter member 10 generally at its upstream end, a urinary irrigation device 12 according to this invention in fluid communication with adapter member 10, drainage tubing 14 in fluid communication with urinary irrigation device 12, and collection bag 16 at the downstream end of the system and in fluid communication with drainage tubing 14." Column 3, lines 61 to 68, emphasis added. Garrett et al. do not disclose or suggest a filter element or a filter module, and therefore do not disclose or suggest a filter module having a closure element.

In rejecting a claim under 35 U.S.C. § 103(a), the Examiner bears the initial burden of presenting a prima facie case of obviousness. In re Rijckaert, 9 F.3d 1531, 1532, 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993). To establish prima facie obviousness, three criteria must be satisfied. First, there must be some suggestion or motivation to modify or combine reference teachings. In re Fine, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988). This teaching or suggestion to make the claimed combination must be found in the prior art and not based on the application disclosure. In re Vaeck, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. In re Mills, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990). Second, there must be a reasonable expectation of success. In re Merck & Co., Inc., 800 F.2d 1091, 231 U.S.P.Q. 375 (Fed. Cir. 1986). Third, the prior art reference(s) must teach or suggest all of the claim limitations. In re Royka, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974). Since Garrett et al. do not teach, or even suggest, all of the limitations of claim 36 as more fully set forth above, it is respectfully submitted that Garrett et al. do not render obvious claim 36.

It is respectfully submitted that the cases of In re Fine, supra, and In re Jones, 21 U.S.P.Q.2d 1941 (Fed. Cir. 1992), make plain that the Office Action's generalized assertions that it would have been obvious to modify or combine the references do not properly support a § 103 rejection. It is respectfully submitted that those cases make plain that the Office Action reflects a subjective "obvious to try"

standard, and therefore does not reflect the proper evidence to support an obviousness rejection based on the references relied upon. In particular, the Court in the case of In re Fine stated that:

> The PTO has the burden under section 103 to establish a *prima facie* case of obviousness. It can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references. This it has not done. . . .
>
> . . . .
>
> **Instead, the Examiner relies on hindsight in reaching his obviousness determination. . . . One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.**

In re Fine, 5 U.S.P.Q.2d at 1598 to 1600 (citations omitted; italics in original; emphasis added). Likewise, the Court in the case of In re Jones stated that:

> Before the PTO may combine the disclosures of two or more prior art references in order to establish *prima facie* obviousness, there must be some suggestion for doing so, found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. . . .
>
> **Conspicuously missing from this record is any evidence, other than the PTO's speculation (if it be called evidence) that one of ordinary skill . . . would have been motivated to make the modifications . . . necessary to arrive at the claimed [invention].**

In re Jones, 21 U.S.P.Q.2d at 1943 & 1944 (citations omitted; italics in original).

That is exactly the case here since it is believed and respectfully submitted that the present Final Office Action offers no evidence whatsoever, but only conclusory hindsight, reconstruction and speculation, which these cases have indicated does not constitute evidence that will support a proper obviousness finding. Unsupported assertions are not evidence as to why a person having ordinary skill in the art would be motivated to modify or combine references to provide the claimed subject matter of the claims to address the problems met thereby. Accordingly, the Office must provide proper evidence of a motivation for modifying or combining the references to provide the claimed subject matter.

More recently, the Federal Circuit in the case of In re Kotzab has made plain that even if a claim concerns a "technologically simple concept" -- which is not the case here -- there still must be some finding as to the "specific understanding or principle within the knowledge of a skilled artisan" that would motivate a person having no knowledge of the claimed subject matter to "make the combination in the manner claimed," stating that:

> In this case, the Examiner and the Board fell into the hindsight trap. The idea of a single sensor controlling multiple valves, as opposed to multiple sensors controlling multiple valves, is a technologically simple concept. With this simple concept in mind, the Patent and Trademark Office found prior art statements that in the abstract appeared to suggest the claimed limitation. But, there was no finding as to the specific understanding or principle within the knowledge of a skilled artisan that would have motivated one with no knowledge of Kotzab's invention to make the combination in the manner claimed. In light of our holding of the absence of a motivation to combine the teachings in Evans, we conclude that the Board did not make out a proper prima facie case of obviousness in rejecting [the] claims . . . under 35 U.S.C. Section 103(a) over Evans.

In re Kotzab, 55 U.S.P.Q.2d 1313, 1318 (Fed. Cir. 2000) (emphasis added). Again, it is believed that there have been no such findings.

Therefore, reversal of the 35 U.S.C. § 103(a) rejection, and allowance of claim 36 is respectfully requested.

As for claims 37, 38, 59 to 62 and 65 to 69, which depend from independent claim 36 and therefore include all of the limitations of claim 36, Applicants submit that these claims are patentable for at least the reasons submitted above in support of the patentability of claim 36. Therefore, reversal of the 35 U.S.C. § 103(a) rejection, and allowance of claims 37, 38, 59 to 62 and 65 to 69 is respectfully requested.

B. The Rejection of Claims 36 to 38, 60 to 64 and 66 to 69 Under 35 U.S.C. § 103(a) as Unpatentable Over Merry et al. Should Be Reversed

Claims 36 to 38, 60 to 64 and 66 to 69 stand finally rejected under 35 U.S.C. § 103(a) as unpatentable over Merry et al. Appellant respectfully submits that this rejection of claims 36 to 38, 60 to 64 and 66 to 69 should be reversed for at least the following reasons.

Merry et al. purport to describe a self-sealing percutaneous tube (e.g. catheter) introducer having a sealing mechanism to prevent blood or fluid leakage. Merry et al. state that the introducer includes spaced sealing gaskets adapted to surround the tube, a distal sealing element being planar and having a slit. Merry et al. further state that the proximal sealing element is conical and has an annular opening at its distal and small end. Merry et al. also state that the introducer may include a side arm flushing member and/or a female luer lock connection at its proximal end.

The Final Office Action states that "Merry et al. teach a closure element (26, 29) in a medical device comprising a first gasket (26) with a resiliently deformable Y-slit (27) and a second gasket (29) with a central opening (31) wherein gaskets are made of silicone and resilient slit prevents entry of air (see figures 1-4; col. 4, line 37 – col. 5, line 18)." Final Office Action at page 4. The Final Office Action also states that "[s]pacer ring (28) and valve body (11) hold the closure element and thus satisfies the means for fastening the closure element to a connecting element (see figure 1)." Final Office Action at page 4. The Final Office Action admits that "[c]laim 36-38, 60, 62-63 and 66-68 essentially differ from the device of Merry et al in reciting a filter module." Final Office Action at page 4. However, the Final Office Action concludes that "[i]t would have been obvious to a person of ordinary skill in the art to incorporate a closure element of Merry et al in a common medical filter module such as a dialyzer, hemofilter and ultrafiltration filters with a plurality of connections for providing sterile connections between a tubing and the filter module." Final Office Action at page 4.

Respectfully, Merry et al. do not render unpatentable claim 36 for at least the reason that Merry et al. do not disclose, or even suggest, all of the limitations of claim 36. For instance, Merry et al. do not disclose, or even suggest, a filter module having a closure element, as recited in claim 36. As set forth above, the Specification states at page 7, lines 18 to 20 that "Figure 1B shows a housing 20 having an opening 30, for example of a filter module, for accommodating closure element 10 according to this invention" and at page 2, lines 13 to 16 that "a closure element according to this invention has a simple design and provides a reliable and sterile seal of a medical object, such as a filter module, during and after sterilization."

In contrast, Merry et al. purport to describe a self-sealing percutaneous tube, such as for a catheter. Specifically, Merry et al. states that "[t]he present field

is surgical percutaneous introduction of elongated cylindrical devices such as hollow catheters, electrodes, biopsy instruments, closed-end cardiovascular catheters, etc. into blood vessels whereby leakage of blood is prevented through the introducer and optionally providing a side port for blood sampling, infusion, pressure monitoring or aspiration of fibrin deposits or other debris." Column 2, lines 10 to 17. Merry et al. also states that "[t]he present invention provides a self-sealing percutaneous tube introducer." Column 2, lines 20 to 21. Merry et al. do not disclose or suggest a filter element or a filter module, and therefore do not disclose or suggest a filter module having a closure element.

Therefore, reversal of the 35 U.S.C. § 103(a) rejection, and allowance of claim 36 is respectfully requested.

As for claims 37, 38, 60 to 64 and 66 to 69, which depend from independent claim 36 and therefore include all of the limitations of claim 36, Applicants submit that these claims are patentable for at least the reasons submitted above in support of the patentability of claim 36. Therefore, reversal of the 35 U.S.C. § 103(a) rejection, and allowance of claims 37, 38, 60 to 64 and 66 to 69 is respectfully requested.

9. CONCLUSION

In view of the foregoing, it is respectfully submitted that Garrett et al. do not anticipate claims 36 to 38, 59 to 62 and 65 to 69, and that Merry et al. do not render obvious claims 36 to 38, 60 to 64 and 66 to 69.

Reversal of the final rejections of claims 36 to 38 and 59 to 69 is therefore respectfully requested.

Respectfully submitted,

Dated: June 24, 2004 TCH

By: _____

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APPENDIX A

36. A filter module having a plurality of connections for supplying or removing a fluid from a device, at least one of said connections comprising:

a closure element;

a wall formed in the closure element having an automatically closing slit-shaped indentation forming a germ-proof closure when closed; and

means for fastening the closure element to a connecting element disposed adjacent to the wall.

37. The filter module according to claim 36, wherein the filter module is configured for one of dialysis, hemofiltration and ultrafiltration.

38. The filter module according to claim 36, wherein the closure element comprises one of an inside surface forming a germ-proof closure with the outside surface of the connecting element, and an outside surface forming a germ-proof closure with an inside surface of a bushing-like connection.

59. The filter module according to claim 36, wherein the closure element is substantially cylindrical, the fastening means include a cylindrical surface, and the slit-shaped indentation is formed on an end face of the cylindrical closure element.

60. The filter module according to claim 36, wherein the closure element is symmetrical about an axis of the connection.

61. The filter module according to claim 36, wherein the slit-shaped indentation is in the shape of a cross or a star.

62. The filter module according to claim 36, further comprising a second wall opposite to the wall having the indentation, the second wall having an opening for passage of a fluid.

63. The filter module according to claim 62, wherein a middle portion of the indentation is aligned with the opening.

64. The filter module according to claim 62, further comprising a surface extending around the opening in the second wall, the surface lying in a plane substantially perpendicular to a joining direction of the closure element to the connecting element.

65. The filter module according to claim 36, wherein the closure element is formed of one piece.

66. The filter module according to claim 36, wherein the wall and the closure element are made of plastic.

67. The filter module according to claim 66, wherein the plastic is silicone.

68. The filter module according to claim 36, wherein the wall comprises a spring element acting in a radial direction.

69. The filter module according to claim 36, wherein the slit-shaped indentation forms a germ-proof closure adapted to withstand a pressure difference up to about ±0.25 bar.